

REMARKS

Claims 1-26 are pending. Claim 26 has been withdrawn from consideration.

Claims 1 and 15-17 have been amended without prejudice or disclaimer of subject matter.

Claims 1, 15-17 and 26 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Rejections Under 35 USC §103

Claims 1-6 and 17-21 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,432,441 (*Bealin-Kelly et al.*) in view of U.S. Patent No. 4,271,142 (*Puglia et al.*) and U.S. Patent No. 4,260,596 (*Mackles*). Claims 1-25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,060,078 (*Lee*) in view of U.S. Patent No. 4,800,087 (*Mehta*), U.S. Patent No. 4,753,790 (*Silva*), U.S. Patent No. 4,260,596 (*Mackles*), and U.S. Patent No. 6,432,442 (*Buehler et al.*). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Among the noteworthy features of the texture masking dosage form recited in Claim 1 are (a) a unitary soft core, which is comprised of a plurality of active agent particles having an average size of from about 150 μm to about 500 μm , a hydrocolloid, and water, and (b) a brittle shell encasing the soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500 μm to about 3000 μm , wherein the weight ratio of active agent particles to shell is from about 1.0:0.5 to about 1.0:15 in the texture masking oral dosage form.

As stated in Applicants' specification, the inventive dosage form masks the grittiness of the active agent particles contained therein. *See* Specification, p. 3, paragraph [0011].

Bealin-Kelly et al., discussed previously, discloses a throat drop that has an edible shell (from 60% to 95%) and an aqueous filling (from 5% to 40%). The filling includes a throat relief agent, water, and a vesicle-forming agent, which encapsulates the throat relief agents. *Bealin-Kelly et al.* states that the vesicles are preferably formed using phospholipids and have a number average particle size of from about 1 to about 100 μm .

As noted previously, the vesicles disclosed in *Bealin-Kelly et al.* are NOT the same as the active agent particles recited in Claim 1. Nonetheless, solely in the interest of expediting examination and without prejudice or disclaimer of subject matter, Applicants have amended Claim 1 to indicate that the plurality of active agent particles have an average particle size of from about 150 μm to about 500 μm . As such, the vesicles disclosed in *Bealin-Kelly et al.* do not fall within the amended claimed range of from about 150 μm to about 500 μm . Moreover, nothing in *Bealin-Kelly et al.* would lead one to believe that the throat agent (i.e., active agent particles), has a gritty texture such that some form of texture masking would be desirable. As such, Claim 1 is patentable over *Bealin-Kelly et al.*

Puglia et al. and *Mackles* have been discussed previously, and do not remedy the deficiencies of *Bealin-Kelly et al.*, since *Puglia et al.* and *Mackles* do not teach or suggest active agent particles having an average size of from about 150 μm to about 500 μm .

As such, claim 1 is patentable over *Bealin-Kelly et al.*, *Puglia et al.* and/or *Mackles*, whether considered separately or in any proposed combination.

Lee, as noted by the Examiner, does not teach (i) the use of ibuprofen in the disclosed dosage form, (ii) the particle sizes for the active agent, (iii) an outer shell that is about 20% to about 50% of the total weight of the dosage form, or (iv) that the

outer shell has a thickness of about 500 to 3000 microns. *See* Office Action dated December 28, 2009, p. 5, lines 10-14.

On page 10 of the present Action, the Examiner states that “[s]econdary references are cited solely for the teachings of well known candy coating thickness, as well as analgesic active agent having bitter taste such as ibuprofen.” *See* Office Action, p. 10, lines 18-20.

Applicants’ respectfully submit that the statement noted above strongly suggests that bits and pieces were carefully selected from each of the four secondary references to remedy the deficiencies of *Lee* - thus, recreating Applicants’ invention only after reading Applicants’ specification. Accordingly, Applicants maintain that the proposed combination of *Lee*, *Mehta*, *Silva*, *Mackles*, and *Buehler et al.* is based upon hindsight reconstruction.

Each feature of Applicants’ invention has been reconstructed starting with *Lee*, alleging that *Lee* contains an enabling disclosure of a dosage form with a unitary core. The claimed active agents were taken from *Mehta*. Then from *Silva*, the Examiner selects the disclosure of a crunchy coating that surrounds a substantially anhydrous core. Next, *Mackles* is relied upon for teaching the thickness of a shell surrounding a core. Finally, *Buehler* is relied upon for disclosing a core that includes water and a hydrocolloid.

In piecing together all the elements of the present invention, the Examiner has dismissively stated that “it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning” and that the “[s]econdary references are cited solely for the teachings of well known candy coating thickness, as well as analgesic active agent having bitter taste such as ibuprofen.” *See* Office Action, p. 10, lines 4-6 and lines 18-20. Applicants acknowledge the Examiner’s statements, but respectfully request

that the Examiner clarify why one skilled in the art would be motivated to make each of the substitutions or modifications. The Examiner herself has acknowledged “that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or *motivation* to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” See Office Action, p. 10, lines 10-14 (*emphasis added*). Applicants are unclear as to whether any such motivation has been enunciated or expressed by the Examiner and/or in the secondary references as to why the substitutions or modifications are appropriate. In the absence of such clarification, Applicants are left to conclude that the Examiner’s focus is solely on recreating the invention, with no appreciation or understanding of the problem Applicants were faced with.

Accordingly, Applicants respectfully request that the Examiner explain (i) why one skilled in the art would be motivated to modify the soft cores taught in *Lee*, *Mackles*, and/or *Silva*, which are understood to be anhydrous, with the core taught by *Buehler* which includes water and a hydrocolloid. Moreover, (ii) why would one skilled in the art looked to *Silva* to include a crunchy coating to surround a substantially anhydrous core. “[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” MPEP 2141.III, quoting *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007). Applicants maintain that without the benefit of seeing and reading Applicants’ specification which teaches the presently claimed invention, one skilled in the art would not have modified the core in such a manner. Therefore, Applicants maintain that the § 103 obvious rejections of the pending claims are based on hindsight reconstruction, which is not

permissible. Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

Claims 15, 16 and 17 are directed to compositions that are similar to the composition of Claim 1 in many respects. Claims 15, 16 and 17 all include the features of Claim 1. Accordingly, for at least the same reasons discussed above for Claim 1, Claims 15, 16 and 17 are patentable over the proposed combination of *Bealin-Kelly et al.*, *Puglia et al.* and/or *Mackles*, or the proposed combination of *Lee*, *Mehta*, *Silva*, *Mackles*, and/or *Buehler et al.*

The remaining claims directly or indirectly depend from Claims 1, 15, 16 or 17. Therefore, each of the remaining claims is also patentable for the reasons stated above.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time the claimed invention was made in light of the references cited. Thus, Applicants respectfully request that this rejection under 35 USC §103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response,
please charge the fees to our Deposit Account No. 10-0750/MCP0281USNP/VT.

Respectfully submitted,

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